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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,446	10/24/2000	Suzana Petanceska	0630/1G184-US1	2608
32801	7590	02/10/2004		
DARBY & DARBY P.C. P.O. BOX 5257 NEW YORK, NY 10150-5257			EXAMINER DI NOLA BARON, LILIANA	
			ART UNIT	PAPER NUMBER
			1615	19
DATE MAILED: 02/10/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/695,446

Applicant(s)

PETANCESKA ET AL.

Examiner

Liliana Di Nola-Baron

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 7-19 and 26-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 20-25 and 31-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I, claims 1-6 and 20-25 in Paper No. 18 is acknowledged. The traversal is on the ground(s) that the restriction requirement was submitted almost three years after filing of the application, and the subject matter of pending claims 1-30 has already been searched and examined on the merits. This is not found persuasive because inventions I, II and III are unrelated, have different modes of operation and different effects. Group I is directed to a method of reducing a level of amyloid- $\beta$  in vivo, Group II relates to a diagnostic method in vitro, and Group III is drawn to a method of testing in vivo. The inventions are distinct and have a separate status in the art.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-6, 20-25 and 31-33 will be examined in this office action. Claims 7-19 and 26-30 are withdrawn from consideration.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-6, 20-25 and 31-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Notelivitz et al. (U.S. Patent 6,524,616).

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The 102(e) date of the reference is the earliest U.S. filing date for which a benefit is properly sought via § 119(e) and/or 120. The earliest filing date of U.S. Patent 6,524,616 is June 25, 1999, which is prior to the filing date of the provisional application, to which the instant application claims benefit.

The patent provides a method for treating or retarding neurodegeneration and cognitive decline and dysfunction associated with Alzheimer's disease (AD), aging and other dementia disorders, said method comprising administering compositions comprising mammalian estrogen (See col. 1, lines 15-26 and col. 10, lines 55-60). With regard to claims 1, 2 and 20, the patent teaches that estrogen reduces the deposition of  $\beta$ -amyloid in the brain (See col. 12, lines 53- 67). The amount of mammalian estrogen in the compositions disclosed by the patent is 0.2-2.0 mg, which is in the amount range claimed by Applicant in claims 31 and 33, and the patent teaches estradiol, specifically 17- $\beta$  estradiol, and conjugated equine estrogens (CEE) as estrogen used in the method of the invention (See col. 10, line 60 to col. 11, line 2), as claimed in instant claims 3, 4, 21 and 31-33. The method disclosed by the patent, which comprises administering the same compounds claimed by Applicant in the same amount ranges, has inherently no effect on soluble APP levels, as claimed in instant claims 1 and 20.

With respect to claims 5, 6 and 25, since the method and compositions disclosed by the patent and those claimed by Applicant are the same, and the compositions in both the patent and the instant application are administered to patients affected by or at risk of developing AD, the amyloid- $\beta$  peptides are inherently the same and the method inherently reduces the ratio of A $\beta$ 42 to A $\beta$ 40.

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Regarding claim 22, the patent teaches that rats were fed with estradiol diet for 10 months (See Example 1, col. 15, lines 28-49). With respect to claim 23, the patent teaches that all routes of administration of the compositions may be used, and includes pills, capsules and tablets, with acceptable carriers (See col. 13, lines 33-43). With regard to claim 24, the method disclosed by the patent is directed to treat dysfunctions associated with AD (See col. 1, lines 15-26).

The method and compositions disclosed by Notelivitz et al. meet the limitations of claims 1-6, 20-25 and 31-33 of the instant application, as the patent provides methods to reduce the level of amyloid- $\beta$  comprising administering estrogen. Thus, the patent anticipates the claimed invention.

#### *Response to Arguments*

4. Applicant's arguments, filed on January 3, 2003, with respect to the rejection(s) of claim(s) 1-30 have been fully considered and are persuasive, since the prior art is directed to methods affecting the expression and synthesis of APP. Therefore, the rejections of record have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the newly found prior art.

#### *Conclusion*

5. Claims 1-6, 20-25 and 31-33 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 571-272-0592. The examiner can normally be reached on Monday through Thursday, 8:30AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

*Sho3*

January 29, 2004

  
**THURMAN K. PAGE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**